

DECLARATION OF DR. STEVE R. ROFFLER UNDER 37 CFR 1.132

I, Steve R. Roffler, residing at Yen Geo Yuan Road, Section 2, Lane 61, Alley 4, No. 14, 3F, Taipei, Taiwan hereby declare that:

1. I received my bachelor degree from The University of Washington in Chemical Engineering in 1981 and a Ph.D. degree from the University of California, Berkeley in Chemical Engineering in 1986. I did my postdoctoral research from 1987 to 1991 at the National Defense Medical Center, Taipei, Taiwan and Institute of Biomedical Sciences, Academia Sinica, Taipei, Taiwan. I held the position of Assistant Research Fellow from 1991 to 1998 at the Institute of Biomedical Sciences, Academia Sinica, Taipei, Taiwan. I have been an Associate Research fellow since 1998 at the Institute of Biomedical Sciences, Academia Sinica, Taipei, Taiwan.

2. I am a co-inventor of the U.S. patent application Serial Number 09/520,255 entitled "Monoclonal Antibody for Analysis and Clearance of Polyethylene Glycol and Polyethylene Glycol-Modified Molecules" by Steve Roffler, Tian-Lu Cheng and Pin-Yi Wu, filed on March 7, 2000, claiming priority of the previous provisional application Serial Number 60/136,522, filed on May 28, 1999.

3. I am also the corresponding author of the article entitled "Accelerated Clearance of Polyethylene Glycol-Modified Proteins by Anti-Polyethylene Glycol IgM", Bioconjugate Chemistry, 10:3, 520-528, by Tian-Lu Cheng, Pin-Yi Wu, Ming-Fang Wu, Ji-Wang Chern and Steve R. Roffler. This article was published on April 17, 1999.

4. Both of the above patent application and the article were prepared based on the same research work conducted in my laboratory in the Institute of Biomedical Sciences, Academia Sinica, Taipei, Taiwan during the period December 1993 to September 1998 under my direction and control.

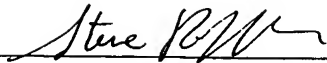
5. Ming-Fang Wu is a researcher in the College of Medicine, National Taiwan University, Taipei, Taiwan. J-Wang Chen is a professor in the School of Pharmacy, National Taiwan University, Taipei, Taiwan. They were not named as inventors in the above patent application because they did not make any intellectual contributions to the claimed invention.

6. Ming-Fang Wu was a co-author of the above article because he made tissue sections of the liver, kidneys and spleen of drug-treated mice and subsequently examine the tissue sections for organ pathology. This data is represented by Figure 7 in the above article. Ji-Wang Chern provided laboratory space and direction on the synthesis of the glucuronide prodrug BHAMG. This drug was employed in some experiments described in the above article.

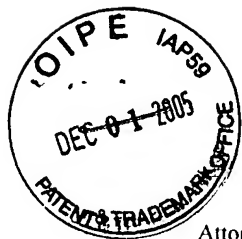
I declare under penalty of perjury that the above is true and correct to the best

of my personal knowledge.

Dated: February 21, 2002

  
Steve R. Roffler

2/21/2002



Attorney Docket # 4910-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

In re Application of

Steve ROFFLER et al.

Serial No.: 09/520,255

Filed: March 07, 2000

For: Monoclonal-Antibody For Analysis And  
Clearance Of Polyethylene Glycol And  
Polyethylene Glycol-Modified Molecules

Assistant Commissioner for Patents  
Washington, DC 20231

Examiner: Holleran, A.

Group Art: 1642

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on  
June 29, 2001  
(Date of Deposit)  
Yunling Ren  
Name of applicant, assignee or Registered Representative  
Signature  
June 29, 2001  
Date of Signature

STATEMENT

SIR:

The attorney of record of this application hereby states that the deposit of hybridoma cells AGP3 have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application, and that the deposit will be replaced if viable samples cannot be dispensed by the depository. A copy of a certificate of deposit is attached herewith.

Respectfully submitted,  
COHEN, PONTANI, LIEBERMAN & PAVANE

By

Yunling Ren

Reg. No. 47,019

551 Fifth Avenue, Suite 1210

New York, New York 10176

(212) 687-2770

Dated: June 29, 2001

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## CHINA CENTER FOR TYPE CULTURE COLLECTION

Wuhan University, Wuhan 430078 P. R. China Fax: (027)87853833, E-mail: cctcc@wbu.edu.cn

### BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

TO: (Name and Address of Depositor or Attorney)

Lee and Li, Attorneys-At-Law

Deposited on Behalf of:

Academia Sinica, Taiwan

Identification Reference by Depositor:

Murine hybridoma cell line AGP3

CCTCC Designation:

CCTCC V 200001

The deposit was accompanied by: \_\_\_\_\_ a scientific description ☒ a proposed taxonomic description indicated above.

The deposit was received Jan. 13, 2000. by this International Depository Authority and have been accepted.

#### AT YOUR REQUEST:

We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample.

The viability of the culture cited above was tested Jan. 28, 2000. On that date, the culture was viable.

International Depository Authority: China Center for Type Culture Collection (CCTCC).

Signature of person having authority to represent CCTCC.

Date: Jan. 28, 2000

Chengxiang Feng, Deputy Director of CCTCC

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